

USSN 09/718,803
Response and Amendment

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REMARKS

Claims 1, 3-7, 9 and 10 are currently pending. Claim 1 has been amended to recite "isolated" peptide. Basis for this amendment is found in the specification, for example, on page 5, and therefore no new matter has been added. Claims 7 and 10 have been amended to recite additional process steps. Basis for this amendment is found in the specification on page 3, for example, and therefore no new matter has been added. Entry of the amendments to the claims is respectfully requested.

Rejections under 35 U.S.C. §102

Claims 1, 3 and 6 are rejected under 35 U.S.C. §102 (b) as allegedly anticipated by published PCT application WO 98/42840. This rejection is respectfully traversed.

Claims 1, 3 and 6 are based on the discovery that a GHS-R binds the peptide of residues 24 to 37 of SEQ ID NO: 2 (zsig33 peptide), and therefore that a reversible peptide-receptor complex can be formed with that peptide and that receptor. WO 98/42840 describes the administration of the zsig33 peptide to the stomachs of rats or administered to mice, to induce stomach contractions or increase glucose absorption in the animals. The Examiner has alleged that the GHS-R are inherently expressed in the stomach and GI track of the animals and therefore WO 98/42840 inherently anticipates claims 1, 3 and 6. Applicants do not agree. In order to anticipate in accordance with 35 U.S.C. §102 (b), a reference must teach every aspect of the claimed invention, either explicitly or inherently. Applicants point out that the instant claims are not drawn to a method of administering a zsig33 peptide to an animal to produce a biological effect. Rather, the claims are drawn to forming a peptide receptor bond with a particular receptor, a GHS-R. WO 98/42840 does not describe the receptor to which the zsig33 peptide binds to produce the described biological effect. Applicants point out in the instant application that about the time of filing of WO 98/42840, the GHS-R was an orphan receptor, with no known ligand (Howard et al., Science 273: 974-977, 1996, see specification). The instant application identified GHS-R as the receptor for the zsig33 peptide. (See specification at page 8, line 20 to page 9, line 13). This is not described either explicitly or inherently in WO 98/42840. Therefore, Applicants submit that WO 98/42840 does not anticipate claims 1, 3, and 6, and request reconsideration and withdrawal of the rejection of these claims on the basis of U.S.C. §102 (b).

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Rejections under 35 U.S.C. § 103.

Claims 1, and 3- 6 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over WO 98/42840 in view of Arena et al WO 97/21730. This rejection is respectfully traversed.

The Examiner has alleged that it would have been obvious to a person of ordinary skill in the art to use a human cell line expressing GHS-R of SEQ ID NO: 5 with the zsig33 peptide shown in WO 98/42840 based on these disclosures. The Applicants do not agree. WO 98/42840 describes the use of zsig33 on rats and mice to induce stomach contractivity and increase glucose absorption. WO 97/21730 describes growth hormone secretagogue receptors for rat, human and swine. This second application does not appear to describe SEQ ID NO: 5 of the instant invention since the human receptor sequences shown on Figures 7, 10 and 12 are not SEQ ID NO: 5. This application describes the use of these receptors to bind growth hormone secretagogue ligands to increase growth hormone secretion, not to increase stomach contractions or increase glucose absorption. WO 98/42840 does not describe or suggest a receptor to which the zsig33 peptide might bind, nor suggest that zsig33 is a growth hormone secretagogue. Therefore, these references in combination do not suggest or describe the claimed subject matter of claims 1, or 3-6. On the basis of the arguments presented above, Applicants request that the rejection of claims 1 and 3-6 on the basis of 35 U.S.C. §103(a) be reconsidered and withdrawn.

Rejections under 35 U.S.C. §112, second paragraph

Claims 7, 9 and 10 are rejected on the basis of 35 U.S.C. §112, second paragraph, as allegedly incomplete due to omitting essential steps. This rejection is respectfully traversed.

Claims 7 and 10 have now been amended to recite additional process steps. Basis for these amendments is found on page 3 of the specification. Therefore, on the basis of the amended claims, Applicants request reconsideration and withdrawal of the rejections of claims 7, 9 and 10 on the basis of 35 U.S.C. §112, second paragraph.

Rejections on the Basis of 35 U.S.C. §101

Claims 1, and 3-6 are rejected on the basis of 35 U.S.C. §101. The Examiner has alleged that these claims are directed to non-statutory subject matter that reads on a naturally occurring *in vivo* process. This rejection is respectfully traversed.

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Claim 1 has now been amended to recite contacting the receptor with an isolated peptide. According to the specification, page 5, an "isolated" polypeptide is "found in a condition other than its natural environment". Therefore, Applicants submit that the method now recited in claim 1 does not read on a naturally occurring process. Therefore, on the basis of the amendment to claim 1, Applicants request that the rejection of claims 1, and 3-6 on the basis of 35 U.S.C. § 101 be reconsidered and withdrawn.

Conclusions

Applicants request that the amendments to the claims shown above be entered, and that on the basis of these amendments and the arguments presented above, the rejection of claims 1, 3-7, 9 and 10 be reconsidered and withdrawn, and that these claims be found allowable. Applicants invite the Examiner to call the number below if it would be helpful in advancing the prosecution of this application.

Respectfully submitted,



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